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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,380	07/12/2006	Joshua Shua-Haim	PN/4-33146A	3361

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,380	SHUA-HAIM ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5 and 13-18* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 13, 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed August 04, 2008 has been received and entered into present application. Claims 6-12 were canceled and claims 13-18 were added by applicant. Claims 14-16, and 18 are withdrawn as subject matter of the non-elected invention. Thus claims 5, 13, and 17 are pending.

Applicants' arguments, filed August 04, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

In applicant's newly added claims 13-18, applicant has added claims directed towards a combination therapy method of treatment including compounds of formula I and a long list of other active agents. The special technical feature of the those claims is the interaction of the two drugs together and their combined effect on the patient, this is different from the special technical feature of claims 5, 13, and 17 where only compounds of formula I are present and its is only the interaction of that single compound upon the patient that is the special technical feature. These are two different species, and since applicant elected a single compound therapy, claims 14-16, and 18 are withdrawn as pertaining to the non-elected invention. It is further added that the withdrawn claims require components that are not required in the elected claims, and

that these new components would require a new search, thus creating burden on the examiner if these claims were not withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 13, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claim 5, applicant claims a method of treating behavioral agitation comprising administering compounds of formula 1, the elected species being monhydroxy-carbamazepine. Applicant has not shown their invention such that one of skill in the art at the time of the invention could use this invention as claimed. Applicant has provided direction towards oxcarbazepine, but not monohydroxycarbamazepine. These two compounds would be expected to have different reactivities based on the difference between an oxo and a hydroxy group, and one of skill in the art would not know without undue experimentation whether the elected species would in fact treat behavioral agitation the same way that oxcarbazepine would.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The quantity of experimentation would be large (1) due to the lack of direction or examples provided towards the elected compound (2,3), especially since treatment of behavioral agitation and Alzheimer's are complicated and unpredictable (7). The nature of the invention is treatment of behavior agitation in a patient with Alzheimer's disease or dementia (4) and the state of the prior art is such that the mechanism of action for the elected species is not well known, and neither are treatments for behavior agitation or Alzheimer's disease (5). The skill of those in the art is very high (6), however the breadth of the claims is large due to the large number of possible manifestations of behavioral agitation (8).

The new reasoning for the rejection is due to the amendment in the claims, and an attempt to clarify the rejection by the previous examiner. Applicant's arguments

were carefully considered but are not found persuasive and thus this rejection is **maintained.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Schindler et al. (US 3,637,661), already of record, for the reasons set forth at pages 8-9 of previous office action dated March 18, 2008, of which reasons are herein incorporated by reference.

In claim 5, applicant claims a method of treatment of behavioral agitation in a subject in need of such treatment, comprising compounds of formula 1, and the elected species being monohydroxycarbazepine. As discussed in the previous office action, Schindler et al. teaches treatment of patients with epilepsy with monohydroxycarbazepine (abstract, column 1, lines 29-38). A patient with epilepsy would be a patient in need of treatment with monohydroxycarbazepine, and thus the method of Schindler et al. would inherently treat behavioral agitation. Furthermore, behavioral agitation is a term that can be interpreted in a variety of ways, the broadest

reasonable interpretation would have to include agitated behavior, such as the rapid or violent action of an epilepsy episode, which as discussed previously, such actions are characteristic of epilepsy, and thus the treatment of Schindler et al. would be expected to treat behavioral agitation. Thus claim 5 is anticipated by Schindler et al.

It is noted that newly added claims 13 and 17 are not included in this rejection, because those require the patient to have Alzheimer's' disease or dementia, which are not taught by Schindler et al. and since the population would be different, Schindler cannot inherently anticipate chose claims.

Applicant has argued that "applicant's claim 5 does not include any disease where agitation is a characteristic, but rather teaches the pathological condition of behavior agitation, commonly experienced by patients suffering from dementia and Alzheimer's disease. " The examiner strongly disagrees, claim 5 requires no specific disease or specific limitations on population, only a subject in need of compounds of formula 1 and any treatment that also treats behavior agitation would anticipate the claims because it does cover each and every element of the claims. Applicant may read more into the claim that is currently presented, and applicant's invention or later claims may be different from the prior art cited, but claim 5 is anticipated by Schindler et al.

This argument is not deemed persuasive and thus the rejection of claim 5 is **maintained.**

Conclusion

Rejection of claims 5, 13, and 17 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614